Program Advisory and Oversight Committee (PAOC) for Quality Standards and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Meeting Summary

February 28-March 2, 2005

Baltimore, Maryland

MONDAY, FEBRUARY 28, 2005

The first day of the PAOC meeting began with a welcome and introduction by Herb Kuhn. The first day's presentations focused on the bid evaluation process; determining payment amounts; the bid solicitation process; and capacity and demand issues. Because time ran out, a topic originally scheduled for the first day of the meeting, rural area and low population density exemption authority, was postponed until the next day. There was no public comment during the first day.

WELCOME AND INTRODUCTIONS

Herb Kuhn opened the third PAOC meeting with a welcome and introductions. After welcoming everyone to the third PAOC meeting, Mr. Kuhn discussed CMS's timeline for the regulation. The proposed regulation would come out over the summer, and would be followed by a comment period. In the fall of 2005, CMS would review the comments to the proposed rule, so that by spring of 2006, CMS could finalize the review and begin the clearance process through OMB and the White House. CMS would publish the final rule in the fall of 2006 and competitive bidding would begin in January 2007.

OVERVIEW OF THE BID EVALUATION PROCESS

Tom Hoerger of RTI presented an overview of the bid evaluation process. The presentation provided a general overview of the process, which would then be presented in significantly greater detail in later presentations at the PAOC meeting. The presentation was broken down into three distinct parts: (1) the bid submission process, (2) evaluating bids and selecting winners, and (3) determining prices.

A significant portion of the presentation was based on the demonstration experience and program requirements. During the demonstration, the bid submission process consisted of bidder education, a bidder's conference, and the request for bids (RFB). The RFBs requested that suppliers submit information on their company, quality, capacity, financial capabilities, and the individual item bids.

During the demonstration, the bid evaluation and winner selection took place in seven steps. In the first step, each supplier's basic eligibility was evaluated. Basic eligibility requirements included having a valid NSC number, no current CMS sanctions, and valid state and local licenses. In the second step, a composite bid was constructed for each supplier based on a volume weighted average of the each supplier's product bids. In the third step, bids were arrayed from lowest to highest composite bid. Then, in the next two steps, supplier quality and financial capabilities were evaluated. Suppliers who did not meet the quality and financial standards were eliminated. In the sixth step, the evaluation panel estimated supplier capacity and in the last step the panel selected the pivotal composite bid. All suppliers with composite bids below the pivotal bids who also met the eligibility criteria, quality, and financial standards were also winners. The pivotal bid was selected such that there were enough winners such that their cumulative capacity could meet the estimated market demand.

Dr. Hoerger then presented, but did not fully discuss, other options not used in the demonstration for selecting the pivotal composite bid. One option was to use the median bid as the composite bid. Another option was to select the bid based on a target number of winners, and a third option was to ex-ante have a target composite bid.

During the discussion, the PAOC committee raised several issues and questions. There was a general concern about the composite bid methodology. Some committee members thought that suppliers might collude on their bids to keep prices high or that individual suppliers that don't supply all the products in a product group might be able to rig their bids.

The PAOC also had questions about quality evaluation and capacity estimation. The PAOC thought quality standards were important and a good idea. However, a couple of members expressed a concern that CMS would not announce the standards or necessary accreditation far enough in advance for suppliers to have sufficient time to meet the standards or get accredited.

The PAOC recognized the tension between additional capacity in the market and a higher price. They also wanted to know how CMS would evaluate capacity and how much excess capacity would CMS want in the market.

DETERMINING PAYMENT AMOUNTS

Dr. Hoerger presented the next presentation, determining payment amounts. The presentation focused on how payment for individual products would be set after the

winners are selected. Dr. Hoerger went through the methodology for two cases. In the first case, suppliers would bid on individual items and in the second case, suppliers would bin on product categories.

Dr. Hoerger first discussed the three basic principles that any payment methodology should adhere to. The first principle is that the suppliers selected offer a lower price than the suppliers not selected. The second principle is that all suppliers are paid the same price. This second principle is actually required by the MMA. The third principle is that winning suppliers receive at least as much for the bundle of times as they bid. The payment methodology used in the demonstration met the three basic principles.

When suppliers bid on individual products, the payment methodology is fairly simple. Once the pivotal bid is selected, the program price is set at the pivotal bid and all winning suppliers receive the pivotal bid.

When suppliers bid on product groups, the payment methodology is more complicated. Dr. Hoerger presented the methodology used during the demonstration to evaluate and set individual product prices when suppliers bid on multiple products within a product group. The process involves four steps. In the first step, each supplier's item bids are used to calculate a composite bid. The items weights are common for all suppliers and are equal to the item's share of expected volume in the product category. Separately, supplier eligibility, quality, and financial standards are evaluated. In the second step, the pivotal composite bid is selected and all suppliers meeting the eligibility, quality, and financial standards are selected. In the third step, the winning supplier's individual product bids are adjusted such that each supplier will now have the same composite bid. In the fourth step, the program prices are set at the average of the supplier adjusted bids.

Dr. Hoerger also discussed three intuitive alternative methods for setting prices and showed how each alternative method violates one or more of the three basic principles. The three alternatives were: (1) set the program price at the average bid of the winning suppliers, (2) set the program price at the lowest bid among the winning suppliers, and (3) set the program price as the highest bid among the winning suppliers.

During the discussion, several PAOC members commented on the complexity of the payment methodology. They also expressed concern that the volume weights could allow suppliers to game their bids if all suppliers didn't have the same distribution of products within the product category or if suppliers could manipulate the distribution of products. The committee members also asked what kind of volume weights would be given to new HCPCS or what would happen to the prices (based on volume weights) if at some time during the bid cycle, there was a dramatic shift from one product to another.

Another topic discussed was how broad the product categories should be. Some PAOC members suggested that broader categories would be better because suppliers would be able to achieve economies of scale and beneficiaries could get all their products from one supplier. However, other PAOC members felt that smaller categories would be better because many suppliers provide only a limited line of products and that there would not

be sufficient time for suppliers to form joint ventures for bidding. They also felt that beneficiaries would prefer to have higher quality products and services even if it meant they would have to receive their products from multiple suppliers.

BID SOLICITATION PROCESS

Deborah Healy of RTI presented the bid solicitation process. The presentation outlined the mechanism for soliciting bids, types of items that should be included in the bids, and individuals that should be included on the evaluation panel. A large portion of the presentation was based on the bid solicitation process utilized in the demonstration. The bid solicitation process begins with identifying and notifying potential suppliers that the RFB will be issued. The next step in the bid solicitation process is educating suppliers and assisting suppliers complete the RFBs. In the presentation, several options were presented for educating suppliers including having an ombudsman in the competitive acquisition areas, holding bidders' conferences, and maintaining a website with frequently asked questions.

During the demonstration, a considerable amount of information was collected in the RFBs. The required information fell into 6 categories: (1) supplier identity and description, (2) supplier capacity, (3) supplier quality, (4) supplier financials, (5) product bids, and (6) documentation and references. During the demonstration, bidders could submit their bids either in hard-copy or electronic form. However, bids submitted in hard-copy form required a significant amount of time and resources to be keyed into an electronic form. Consequently, hard-copy bids may not be a cost effective option. The presentation also presented the option of using a secure web-based form to submit the bids.

During the demonstration, supplier bids were evaluated by two separate panels. One panel evaluated supplier quality and bid prices, conducted site visits, checked references, selected winners, and calculated prices. This panel included a quality expert from Benefit Integrity or the NSC, experts on pricing and HCPCS coding, a quantitative analyst, and individuals with first had DME industry experience. Although, not included on the panel during the demonstration, the panel utilized a DME industry consultant and referral agents. The experience of the demonstration was that these were extremely useful and should be considered for the program evaluation panel.

The second panel evaluated suppliers' financials. The financial panel determined the financial standards and evaluated supplier financial documents. The financial panel members included accountants with DME supplier industry experience and accountants with medical provider experience.

The PAOC members were divided on the best method for educating suppliers. One panel member thought that education should be in person with either an ombudsman or a bidders' conference, while others liked the idea of a website, possibly with an interactive question and answer.

During the discussion, the PAOC members also suggested several items that should be included in the RFB and evaluation process. The items included asking how long the supplier had been in business; what other contracts the supplier had; the supplier's volume of Medicare, Medicaid, and dual care business; how long the supplier had supplied the specific product being bid upon; and the names of individuals with a vested stake in winning. The PAOC also said CMS should define how AR should be calculated and should verify that suppliers' computer systems are sophisticated enough to track manufacturer recalls and maintenance.

CAPACITY AND DEMAND ISSUES

Dr. Tom Hoerger presented capacity and demand issues. The presentation discussed options for estimating demand and supplier capacity. CMS needs to estimate demand in order to provide suppliers with an estimate of how large the market is and how much volume they could potentially gain. CMS also needs to estimate demand because a sufficient number of suppliers will need to be selected in order to be certain that there will be sufficient capacity to ensure beneficiary access and that all beneficiaries are served.

Demand can be estimated using either total claims or new patient claims. New patient claims may be more suitable if CMS implements transition policies. Monthly claims data can also be used to measure growth rates for new HCPCS or other products with increased utilization.

Capacity estimation presents more of a challenge. CMS can observe how much a supplier has supplied in the past, but not how much a supplier is willing and able to supply in the future.

Dr. Hoerger presented three different options for estimating supplier capacity. Under the first option, the evaluation panel would base its estimate of supplier capacity on the supplier's current supply figures. Under the second option, the panel would obtain estimates from consultants on an individual supplier's ability to increase supply. Under the third option, the RFB would ask suppliers how many units of a product they are willing to supply.

Independent of which option CMS chooses to implement, one issue that will need to be dealt with is how to estimate capacity for new entrants. Another issue that will need to be dealt with is how to ensure geographic coverage and that there will be sufficient capacity for all products in all areas of the competitive acquisition area.

Most of the PAOC members felt that capacity was not a significant issue; that all suppliers want to grow their business and will even acquire companies in order to expand their geographic reach. A couple of PAOC members suggested that CMS have a section in the RFP where suppliers could certify how much they would be willing to supply.

During the discussion, some of the PAOC members also cautioned that all capacity should not be treated the same. One example was that for some products, like glucose test strips, one supplier could meet the entire market's demand. But, if only two suppliers -- the minimum required under the statute-- are selected, there could be an adverse effect on future competition. Another example was that brick and mortar suppliers are not the same as mail order suppliers. A mail order supplier may be able to meet the entire market demand, but what if a beneficiary forgot to order his product and now needs it as soon as possible.

The PAOC also agreed that geographic coverage was an important issue. Some members suggested that all suppliers must agree to serve all areas within the competitive acquisition area and that small suppliers not be allowed to serve only a subset of the market. Other PAOC members suggested that the CMS divide the competitive acquisition area into smaller areas such as counties and then have suppliers certify capacity for each area separately.

TUESDAY, MARCH 1, 2005

The second day of the meeting focused on financial capabilities of suppliers, supplier standards, accreditation, and the impact of quality standards on small suppliers. A topic that was originally scheduled for discussion on the first day of the meeting, rural area and low population density exemption authority, was also discussed during the afternoon session. Comments from members of the public completed the discussion on the second day of the meeting.

FINANCIAL CAPABILITIES

Elaine Myers of Palmetto GBA presented an overview of the evaluation of financial capabilities during the Demonstration. The presentation described the information collected, the standards used in reviewing the financial information, and pitfalls/lessons learned. Suppliers were measured on a scale from 0-15 and had to score a minimum of 70% in the financial evaluation component to be deemed acceptable. Based on an analysis of the financial ratios, most suppliers were evaluated as unacceptable using the initial standards.

In order to determine financial soundness, Palmetto GBA requested information from the supplier's financial balance sheet, income statement, and credit references from the supplier's primary financial institution. Palmetto examined financial statements provided with the bid information and computed financial ratios to provide indicators of suppliers' performance in the areas of solvency, efficiency, and profitability. The ratios also provided insight into how executives managed assets, controlled inventory, collected on receivables, and other key measures of financial stability. Comparison thresholds were

developed from industry norms calculated by Dunn and Bradstreet. However, Ms. Myers noted that what Dunn and Bradstreet considered to be "standard" may not necessarily be appropriate for the DME industry. Suppliers within the competitive range were required to complete and return Form F with their financial data within ten days. The form requested data for the last two years as well as data for services location and parent company, if applicable.

Several lessons were learned during the financial capabilities assessment process: 1) Suppliers had problems understanding Form F. As a result, the form was reformatted and revised. 2) In an attempt to obtain consistent information, tax returns should be requested from suppliers to support the financial information that they submit. 3) Ratios were difficult to evaluate because of inconsistent data provided by the suppliers. It is important to be specific in data requests to ensure that there is an apples to apples comparison. 4) Collecting reference information is labor-intensive and challenging. 5) Completion of the financial forms was an unpopular request among the suppliers. Consequently, only suppliers within the competitive range were required to submit financial data to the implementation contractor.

Key results and observations from the assessment process include: 1) Several suppliers were identified as having poor collection practices. 2) Many suppliers were new businesses and did not show a profit or have two full years of financial data. 3) Much of the financial information provided by suppliers was inconsistent and/or incomplete. This was in part, due to the use of different accounting methods and practices by the suppliers. 4) Large suppliers were not necessarily the strongest competitors in the financial category. 5) The process for evaluating new businesses with little or no financial data will remain a challenge.

During discussion, several Committee members noted the importance of examining cash flow as an indicator of how the business is managed on a day-to-day basis. Assessment of the balance sheet, credit worthiness, and days outstanding were also deemed important components in examining financial capabilities. Committee members recognized the improbability of conducting a complete financial evaluation at the beginning of the bid process. Moreover, accreditation organizations currently do not have the capability to conduct evaluations of financial standing during the on-site visits. A suggestion was made to collect basic financial information upfront. Allowance of small joint bids was also mentioned as a means of promoting the entry of new players. This would require assessment of both the parent and local companies. Many felt that efforts should be made to ensure that people previously involved with fraudulent activity be deterred from re-entering through a company re-organization under a different name.

SUPPLIER STANDARDS, ACCREDITATION ORGANIZATIONS, AND QUALITY STANDARDS IMPACT ON SMALL SUPPLIERS

The next presentation, by Shula Bernard from RTI, focused on quality standards used during the Demonstration and the currently proposed quality standards domains. Section

302 of the MMA presents the challenges of defining and establishing quality standards and determining who will accredit DME suppliers. Quality standards focus on business structure and processes, provision of products and services, and outcomes pertaining to the effectiveness of products and services to the beneficiary. The Demonstration included the following four features to maintain and promote quality: 1) initial quality evaluation; 2) multiple winners in each product category; 3) quality and service standards; and 4) ombudsman. Quality standards used during the Demonstration pertained to: general quality and service standards; hospital beds and accessories; oxygen contents, equipment, and suppliers; manual wheelchairs and accessories; non-customized orthotic devices; and nebulizer inhalation drugs. Overall, beneficiaries were satisfied with products and services offered during the Demonstration. Where there was a problem with product quality, poor performing suppliers were eliminated in the next round of bidding. Where there was a problem with service, referral agents changed their referrals to select a higher performing supplier.

To obtain a greater understanding of quality standards used by accreditation organizations, RTI conducted telephone and in-person interviews with the Accreditation Commission for Health Care, the American Board for Certification in Orthotics and Prosthetics, the Community Health Accreditation Program, the Compliance Team, and the Joint Commission on Accreditation of Healthcare Organizations. RTI then reviewed the 21 Medicare supplier standards, each accrediting body's standards manual, and CMS Medicare certified provider and supplier standards to look for commonalities and best practices. The proposed quality standards domains include: organizational structure; financial management; human resources; patient/client management; assessment and evaluation of quality; facility and patient environmental safety; ethics/rights, and information management.

The Committee was supportive overall of the proposed quality standards domains during the discussion following the presentation. However, several Committee members saw the need to have a separate domain for compliance. Many felt that businesses need a compliance culture to ensure that compliance is woven throughout the different components of the business. The discussion then turned to the issue of whether pharmacies selling diabetic supplies, walkers, and canes should be required to go under the level of scrutiny as other DME suppliers. One member felt that requiring pharmacies to comply with all quality standards would automatically eliminate a significant number of providers from the business. Others argued that there should not be variation in standards between small and large businesses. There was also some question as to how the standards would be enforced, however CMS has yet to decide on the specifics of enforcement.

ACCREDITATION

The third presentation of the day, given by Linda Smith from CMS, focused on the rationale for accreditation and highlighted a general description of the application process. Intention to protect beneficiary access and ensuring that suppliers provide

quality products and services are two of the primary purposes of accreditation. According to 42CFR 488.1, an accredited provider or supplier is one that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by CMS in accordance with Sec. 488.6. Under this approach, DMEPOS suppliers would have to be accredited by a CMS-approved accreditation organization in order to participate in the Medicare program. CMS would maintain oversight of the accreditation organizations to validate the accreditation organizations' survey process and to ensure that their standards continue to meet or exceed CMS standards. The costs of completing the accreditation process range from $1000-$9800 and vary based on the scope of services offered and the size of the business operation.

During discussion, questions were raised by the PAOC concerning an increase in a business's operating costs that results from applying for an participating in the accreditation process. Committee members were also concerned about the capacity of the accreditation organizations to accredit the large number of businesses without accreditation within the given timeline. One member noted that while probably 50% of eligible HME organizations are not accredited, the accreditation organizations are ready to prioritize the businesses in the initial 10 MSAs and are fully prepared to meet capacity in 2007. However, it is important that the providers receive a list of the quality standards in an expedient manner. Many Committee members were supportive of the concept of grandfathering in currently accredited organizations. Suggestions were made to allow time for public comment regarding the accreditation process and to hold two-day conferences in each of the MSAs in an effort to educate suppliers on the quality standards and bid process. Smaller businesses may need more time to prepare for accreditation so it is important that the quality standards be disseminated as soon as possible.

IMPACT OF QUALITY STANDARDS ON SMALL SUPPLIERS

During the next presentation, Shula Bernard outlined RTI's proposed approach for facilitating CMS's understanding of the impact of quality standards and accreditation on small suppliers. During March-April 2005, RTI will conduct focus groups in 3-4 sites across the US and aggregate responses from 40-100 small suppliers. Potential market areas include: Atlanta, Cleveland, Denver, Chicago, Minneapolis, and Raleigh/Durham, NC. Effort will be made to include a wide constituency.

During the discussion, the following comments/suggestions were made:

- Include some participants that have been through the accreditation process
- Some small suppliers may not understand that upholding quality standards will be mandated by law. Potential questions to ask during the focus group might include: How can we help you in implementing the law? How would you rate your current readiness for accreditation? What kind of timeline do you need to be ready for the survey?
- Accreditation organizations may want to develop literature describing the costs and benefits of accreditation in terms of gaining sales, learning opportunities, and development of mission statements.

- While focus groups should consist of suppliers offering a diversity of products, perhaps there could be one or more focus groups that is product line specific.

RURAL AREA AND LOW POPULATION DENSITY EXEMPTION AUTHORITY

Joel Kaiser of CMS gave the next presentation on the exemption of rural and low population areas. According to the MMA, rural areas and areas with low population density within urban areas that are not competitive may be exempted, unless there is a significant national market through mail-order for a particular item or service. The proposed phase-in schedule will include 10 MSAs in 2007, 80 MSAs in 2009, and an undetermined number of MSAs in 2010. There is a possibility of expanding the size of the areas for 2007 and 2009 to include areas adjoining the MSA if the areas are deemed as high competitive areas. The decision regarding the number of areas to phase in beyond 80 will be based on relevant data such as the number of suppliers and allowed services/charges. Starting in 2010, one nationwide competitive acquisition area could be established for select items for which there is a significant national market through mail-order. The regulation must establish a process for determining when a rural area or area with low population density within an urban area is non-competitive. If the decision is made to expand the size of the areas for 2007 and 2009 to include areas adjoining the MSA, CMS must establish a process for determining when such an area is "highly competitive." A number of factors may help determine the level of competition in an area including, but not limited to: total number of suppliers, number of beneficiaries per supplier, total allowed charges for bid items, and allowed charges per beneficiary. CMS must also describe how mail-order supply companies will participate under the competitive acquisition programs in 2007, 2009, and onward.

Following the presentation, one Committee member noted that if existence of a national mail order market for a particular product yields competition in a rural area, the area should not be exempted for the product. The question was also raised as to whether two different bid prices would exist for mail-order and non-mail order suppliers. CMS stated that all suppliers would be reimbursed for the same amount. Another member felt that starting with an initial ten markets was a good approach but urged CMS to thoroughly think through the implementation issues before deciding where to go next and the timeline for proceeding.

PUBLIC COMMENTS

Following the agenda items, members of the public were given the opportunity to speak to the Committee, and twelve individuals requested the opportunity to speak. The first individual stated that when competition is eliminated, technology is curbed. He advocated an open door policy to allow everyone to compete and suggested bringing

prices down by 25% and permitting “the cream to rise to the top.” He concluded by saying that competition drives technology and allows the patient to be better served.

The second individual spoke on behalf of the Association of Dealers in Puerto Rico and said that they have very little information about what is going on. Puerto Rico is a very unique market in which 1% of the 500 suppliers are accredited and 100% of Puerto Ricans speak Spanish. He noted that there is a significant language barrier when it comes to the accreditation manuals and added that there will be translation challenges if their MSA is selected as one of the first 10 MSAs.

The third individual stated that it was important for the SADMERC and DMERCs to coordinate activities. Furthermore, advanced notice of the standards will benefit both payors and suppliers.

One individual felt that accreditation made his organization better in that it ensures that they are doing when they should be doing. However, he added that full accreditation is not a necessity at this point in time, given the limited capacity of the accreditation organizations to conduct 24,000 surveys by 2007. In the interim, he recommended the development of a minimum level of standards that must be met in order to participate in the bid process.

An audience member from one of the accreditation organizations noted that his organization is working hard to prepare for mandatory accreditation. They will consider grandfathering in organizations in order to allow the process to move forward.

One individual urged CMS to consider the history of the HCPC codes since some have been expanded. She also raised caution about the quality vs. quantity of financial information provided by suppliers and stated that an organization’s balance sheet, credit worthiness, and cash flow all are very important financial components to consider. She questioned whether there was sufficient staff to handle the volume of bids and wondered who would enforce quality standards. Finally, she noted that grandfathering was an important consideration to allow people to move forward.

A representative from a state medical suppliers association said that he receives a lot of questions from suppliers about competitive bidding and thought that the state supplier associations might be helpful in disseminating information to suppliers. He was pleased to see that the quality standards recognized the provision of intangible services and hoped that this would also be considered when pricing issues are addressed. He concluded by advocating that financial data and the way in which it is collected remain confidential with no loophole to allow this information to be disseminated.

An individual from one of the accreditation organizations noted that her organization incorporates an assessment of compliance as part of its accreditation process. Providers are also required to monitor claims and collect patient satisfaction data. The accreditation process covers two years, with onsite evaluations conducted annually.

A representative form a major manufacturer urged CMS to preserve a role for specialists since they have a large impact on beneficiary access and choice.

A consultant in the audience noted that 11-13 states truly require DME licensure. She also stated that she has never heard anyone say that accreditation was not helpful. However, the process is very involved and time-consuming. Since businesses often need a lot of assistance with the process, she felt that ensuring that the requirements were succinct and straightforward would be helpful.

Another individual noted that from a supplier standpoint, the more information that CMS can share, the better. He was pleased with the proposed plan for quality standards and added that the sooner the ideas can be fleshed out and distributed, the sooner accreditation organizations and MSAs can be identified. He also stated that financial analysis using relevant and reasonable indicators is critical.

A representative from a drug store association stated he was concerned about diabetic testing supplies, and could not understand why glucose monitors and strips had different HCPCS codes.

The last individual to speak stated that when defining services for competitive bidding, there is room for specialty services. He also said that there is a benefit for suppliers, not just in the 10 MSAs, to obtaining accreditation now as opposed to waiting until later. Regarding the concern of being able to pull out the poor performers, he stated that to some extent, we must rely on certification, fraud, and abuse laws to help address this issue. Finally, when looking at bidders he suggested that CMS ensure that the bidders meet the standards before looking at prices.

WEDNESDAY, MARCH 2, 2005

The third day of the PAOC meeting centered on program monitoring, opportunities for small suppliers, and options for a process for physician authorization of brand or mode of delivery. Public comments rounded out the third and final day of the meeting.

PROGRAM MONITORING

Elaine Myers of Palmetto GBA began the first presentation of the day by providing the rationale for program monitoring: to identify and respond to potential problems on a real-time basis; ensure quality; maintain access; and complement quality standards and the selection process. The three components of program monitoring during the Demonstration consisted of: a formal complaint monitoring system, ombudsmen services, and claims monitoring. A formal complaint reporting mechanism was implemented in each bidding area for beneficiaries, referral agents, and other providers to report problems/difficulties encountered with suppliers during the program. The ombudsman’s

role during the Demonstration was to monitor the site through regular site visits and to serve as a liaison, providing constant communication between the community and project team. The ombudsmen played a key role in the smooth functioning of the Demonstration and had strong support from both beneficiaries and suppliers.

Medicare claims data were also monitored during the Demonstration and allowed staff to spot trends and potential problems. Data analysis elements included: total submitted charges; total allowed charges; total reimbursements; prices for the winning bidder; rentals vs. purchases; choice of supplier; utilization levels; and range of equipment and services offered by suppliers. Data were extracted from DMEPOS claims records of the Statistical Analysis DMEPOS Regional Carrier (SADMERC). The SADMERC was responsible for maintaining and analyzing utilization history for all Medicare DMEPOS claims processed by the four DMERCS. Claims data were obtained from the SADMERC on a monthly and quarterly basis beginning prior to Demonstration startup in each site and continuing throughout each round of bidding.

Following the presentation, discussion focused on the costs and benefits associated with the ombudsmen. Committee members recognized the value of the personal relationships between the ombudsmen and community members/advocacy groups, but questioned the cost of providing such monitoring services. There was also concern that suppliers might switch products for profitability. A suggestion was made to stress a commitment to customer service in the educational workshops and inform suppliers of the expectation. Perhaps there could be communication with disease management firms since they may also have interest in the products that their clients receive from suppliers. Another Committee member suggested that site visits by ombudsmen and accreditation organizations be coordinated so that information can be pulled at the same time and there is less burden on the suppliers. There was also discussion of the resolution of complaints during the Demonstration. Ombudsmen and toll-free numbers were the primary modes for receiving complaints. Complaints pertained primarily to misinformation or the need for clarification to beneficiaries and suppliers on how the Demonstration worked. Only a few suppliers were placed on corrective action plans.

OPPORTUNITIES FOR SMALL SUPPLIERS

The second presentation of the day was given by Tom Hoerger of RTI and highlighted the definition of small suppliers, possible disadvantages of small suppliers in a competitive acquisition, and options for giving small suppliers opportunities in the bid solicitation process. The Small Business Administration (SBA) defines small businesses in the home health equipment rental industry as those bringing in less than $6 million in annual sales. Based on 2002 Census Bureau data, up to 60 percent of DMEPOS suppliers qualified as small businesses using the SBA definition. The CMS regulatory definition defines small suppliers those with fewer than 10 full-time equivalent employees. Possible disadvantages of small suppliers in a competitive acquisition include: cost of submitting a bid may be largely fixed and independent of supplier size; larger companies have lower

costs and higher margins because of economies of scale; and they may not have the capacity to serve all beneficiaries.

Potential rules that might create a level playing field for small suppliers include:

- Select multiple winners.
- Do not require suppliers to provide DME products to all beneficiaries in the competitive biding area.
- Allow suppliers to designate which parts of the competitive bidding area they want to serve.
- Small suppliers may have limited service areas or the areas may be limited to one state within a multi-state MSA.
- Conduct bidding at the product or product category level.
- Allow small suppliers the option to form networks for bidding purposes.
- Pro-active education by CMS.
- CMS could establish more limited financial standards for small suppliers.

Discussion of this section covered many areas. One Committee member pointed out that small businesses are at a disadvantage because referral agents tend to look for a supplier that can provide blanket coverage. Unless there is a SBA provision, referral agents will tend not to recommend small businesses because of the extra time it takes to locate separate suppliers. Another member cautioned against allowing larger suppliers to hide behind what appears to be a smaller company. There was also concern that smaller providers would struggle a lot during the bid process, particularly if they were not previously involved in bidding because they do not know their true costs. A suggestion was made to allow beneficiaries to obtain products/services from non-bid winners at a premium. If a beneficiary preferred to obtain supplies from a non-bid winner, he/she may continue to obtain supplies from the provider at the cost of a co-payment. The provider would then have to agree to sell the supplies at the contracted price. The concept of supplier networks generated a great deal of discussion among the PAOC members. While some felt that networks would allow smaller suppliers to ban together and have a better chance at winning a bid, others felt that eligibility and accountability issues were of significant concern. One member noted that requiring specialty firms to expand to product categories where they have no skills may be inappropriate and a disservice to beneficiaries. Another felt that virtual systems in which the network disbands after completion of the bid process were difficult to manage in terms of enforcing quality standards and determining accountability.

One Committee member felt strongly that pharmacies should be considered a unique class of small business and argued that they provide service to the rural areas and receive visits twice a year from the state board of pharmacy. He felt that since only selected DME supplies are sold at many pharmacies, full accreditation is unnecessary. Another member stated that creating a subset of rules for any group is inappropriate and added that state pharmacy boards do not have the capability to police all areas in question. One member advocated for the exemption of high-end, customized rehabilitation and assistive technology devices and also added that he would like to see the creation of a beneficiary advisory board to work in conjunction with the PAOC.

OPTIONS FOR A PROCESS FOR PHYSICIAN AUTHORIZATION OF BRAND OR MODE OF DELIVERY

Following the discussion of opportunities for small suppliers, Tom Hoerger of RTI reviewed options for a physician authorization process. Physicians can currently authorize and request specific products or modes of delivery. This often relies on informal communication between physicians/referral agents and suppliers. While suppliers are not required to respond to such requests, they often do comply in order to keep the physician's business. The following four options for a physician authorization process were presented to the PAOC: 1) rely on the current, informal system; 2) physicians could specify brand and model on a dedicated for or a modified CMN; 3) suppliers could be required to comply with the request; and 4) suppliers could be required to submit a list of products that they supply and physicians/referral agents could choose from the list. Potential benefits of operationalizing physician authorization include: potential improvement in the physicians' ability to request specific products within HCPCs codes that may improve medical care; it could encourage suppliers to offer higher quality or a broader selection of products; and it may reduce beneficiary dissatisfaction associated with switching of brands/products. Potential costs include: the process could result in the unnecessary provision of expensive or "premium" suppliers; suppliers' costs will increase if they must special order supplies, diversify their inventory, or supply more expensive items; referral agents' burden will increase if they must identify suppliers that can provide a specific item; the process would require an additional form or modification of the CMN; the complexity of specifying products within a HCPCS code could lead to errors.

During the discussion following the presentation, PAOC members were clearly not in favor of physician authorization and felt that it would lead to increased administrative complexity and unnecessary burden for both physicians and suppliers.

PAOC GENERAL COMMENTS

One member asked if responses to questions raised during the October meeting were available. CMS said that they should be available and that they will follow up on the request. Another Committee member was surprised to see that there were no suppliers from the Demonstration present at the meeting and thought it would be helpful to discuss issues with them since they had first-hand experience with the process during the Demonstration. CMS noted that they will follow up on this. One member requested a breakdown of suppliers by supplier type. RTI noted that in their analysis of suppliers in the NSC database, there were 105,565 NSC numbers listed in all product categories (some NSC numbers were listed in more than one category; the number of unique NSC numbers was 88,771); 22,662- DME, 22,946- optical, 6,050-orthotics, 48,552-pharmacies, 5355 - prosthetics. Obtaining a breakdown by the number of unique names

was complicated by the inability to match all affiliates. As a result, the estimates are imprecise. There were approximately 54,000 supplier with unique names by product category; 15,715 DME suppliers with unique names; 14,737 optical, 4,422 orthotics, 15,452 pharmacies, and 3,799 prosthetics.

PUBLIC COMMENTS

The first individual represented one of the accreditation organizations and stated that accreditation should establish quality products, care, patient evaluation, and follow-up. He went on to note that approximately 75% of O&P businesses are small businesses.

The next person to speak stated that limiting Medicare patients to a small number of suppliers will practically guarantee that non-selected suppliers will go out of business. If patients are allowed to go outside of the contract and there are primary and secondary winners, the secondary winners should be able to re-bid in 3 years so that they are not kept out of the game.

An individual representing the home infusion therapists association said that her organization's members are accredited for the most part because their payers require accreditation.

The next individual represented another regional medical equipment dealer's association and noted that of their 131 members, 54% are accredited. If a beneficiary survey were to be conducted, she suggested that the survey/lead letter arrive on company letterhead. Otherwise, beneficiaries may fear that that there are ramifications to participating. She concluded by saying that many suppliers want to be accredited but are unsure of who to select.

FINAL COMMENTS

Rita Hostak stated that people wanting to quote CMS or side conversations from the PAOC meeting should contact Ellen Griffith at the press office: 202-690-6161.